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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/392,842	09/09/1999	SAMUEL P. SAWAN	SUR-008	1863

7278 7590 02/27/2006

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/392,842

Applicant(s)

SAWAN ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 58,60,62-71 and 89-102 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 58, 60, 62-71, 89-102 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Amendment filed on November 11, 2005 has been entered. Claims 58, 60, 62-71, 89-102 are pending.

Prosecution on the elected bigunide polymer specie of poly(hexamethylenebiguanide) ("PHMB"), and water-insoluble organic compound specie of methylene-bis-N,N-diglycidylaniline, ("MBDGA") as set forth in Paper No. 8, is continued.

### ***Double Patenting***

Claims 58, 60, 62-71, 89-102 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-38 of U.S. Patent No. US 6,180,584, claims 1-6 US Patent 6,030,632, claims 1-9, US Patent 5,869,072, claims 1-9, US Patent 5,817,325.

Examiner noted Applicant statement indicating that an appropriate terminal disclaimer will be filed once allowable subject matter is determined.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 89, 92, 95, 98 stand rejected under 35 U.S.C. 102(e) as being anticipated by Fujiwara et al US Patent 5,681,802.

The instant claims are directed to methods of treating skin comprising administering a composition comprising an organic polycationic polymer and an

antimicrobial metallic material which can be rendered substantially water insoluble and wherein the antimicrobial is forming a moisture-resistant film on the skin.

Fujiwara teaches skin-cleansing agents comprising cationic polymers and/or cationic surfactant system with a metal containing material within the scope of the instant claims (see col 3, lines 21-25; col 8, lines 19-25; col 9, lines 5-25; col 77, lines 40-60). The cationic polymer of Fujiwara can be either in the form of cationic conditioner such as polyquaternium 7, 24, or cationic surfactants (see col 5, lines 53-55; col 8, lines 19-22; compositions 3-6). The metallic compounds of Fujiwara's compositions include sodium chloride, sodium sulfonates, or metallic sorbates as preservatives.

Further Examiner points out that all recited preservatives fall within the instant recitation of antimicrobial metallic material because a preservative is viewed as an antimicrobial product and they can be rendered substantially water-insoluble. Thus, the limitations of the compositions described in Fujiwara meets the limitations of the instantly employed compositions.

Since the compositions of Fujiwara meets all elements of the compositions employed in the step (a) of the instant claims, formation of a moisture-resistant film and the properties of the film (i.e. sweat resistant) would be an inherent function of such skin compositions of Fujiwara when it is applied to skin, because such properties or function are inseparable from the composition upon its application to skin.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 58, 60, 62-71, 89-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawan et al WO 95/17152 ('152) in view of Fujiwara US Patent 5,681,802 and Smith US Patent 5,576,006.

Instant claims are directed to methods of treating skin by (a) administering to skin a composition comprising providing antimicrobial activity on skin comprising a biguanide polymer, an antimicrobial metallic material and a skin compatible component and (b) forming a moisture-resistant film on the skin to provide antimicrobial activity.

Sawan '152 teaches that the cross-linking of PHMB with a water-insoluble organic compound such as MBDGA enhances the final activity. Swan also teaches the use of silver salts as a bactericidal metallic material (see pages 25-29, page 65, lines 3-20). Sawan's formulations are readily used topically directly or indirectly (see page 27 last para – page 28, 1<sup>st</sup> para). In fact, Sawan spreads the compositions directly into the eye (see page 60, claims 29-30). Thus, it is well established in the art that silver salts of Swan are bactericidal material and that they are readily used for topical applications. Sawan does not directly teach various topical components such as preservatives, thickeners, emollients, etc... used to make topical formulations for direct skin administration.

Liquid skin cleanser compositions containing skin compatible components such as emollients, thickeners, moisturizing agents and surfactants, in the form of ointment, soap or lotion are well described in the art. Fujiwara discloses liquid skin cleanser compositions in the form of lotion or cream comprising a cationic polymer and a metallic material that falls within the scope of the instant claims as described in page 7 of the

Art Unit: 1617

specification. (see col 5, lines 15-24). Fujiwara also teaches other skin compatible components such as lactic acid and surfactants, thickeners, pH modifiers to formulate a topical cleansing formulation. (col 7, lines 26-col 8, line 25). Fujiwara compositions are in the form of lotion, soap, cream etc.. (see col 9-11). Fujiwara fails to employ silver salts and PHMB in his composition as an additional antimicrobial agent.

Smith is complementary to Fujiwara and Sawan as it provides the state of art for preparing topical PHMB containing lotions (see col 3, line 39-col 4, line 50).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to merely combine the formulations of Sawan and Fujiwara and apply such composition directly to skin to provide antibacterial activity on skin. The ordinary skill in the art would have been motivated to combine the compositions of Sawan and Fujiwara, because it has been held *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980). Thus, instant claims that require no more than mixing together of two conventional antimicrobial compositions and using it topically on skin are viewed to be unpatentable over the cited prior art.

In alternative, since both PHMB and Silver salts, as described by Sawan and Smith, provide antibacterial properties, one of ordinary skill in the art at the time of invention would have been motivated to add them together to skin cleansing

compositions such as those described by Fujiwara to enhance antimicrobial activity of such compositions.

### ***Response to Arguments***

Applicant's arguments filed November 21, 2005 have been fully considered but they are not persuasive.

Applicant argues that the prior art does not teach antimicrobial metallic material, which can be rendered substantially water-insoluble. (see arguments at page 8-9). As the initial matter, the disputed limitation does not positively limit the instant claims. further, applicant has not provided any evidence on record that the prior art compounds can not be rendered substantially water insoluble. In fact, the art is replete with water insoluble metallic material that contains an alkali earth salt. Thus, the rejection are maintained.

### ***Conclusion***

No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1617

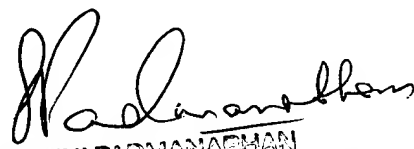
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER